ForPatients
by Roche

Acute Myeloid Leukemia

A Dose Escalation and Expansion Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of RO7283420.

Trial Status	Trial Runs In	Trial Identifier
Completed	10 Countries	NCT04580121 2020-000216-30 WP42004

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

An Open-Label, Multi-Center, Phase I Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of RO7283420 as a Single Agent in Hematologic and Molecular Relapsed/Refractory Acute Myeloid Leukemia

Trial Summary:

This open-label, entry-into-human (EIH) study will evaluate the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics of RO7283420. Escalating doses of RO7283420 will be administered to participants with Acute Myeloid Leukemia (AML) in order to determine the maximum tolerated dose (MTD) and/or recommended Phase II dose (RP2D).

Hoffmann-La Roche
Sponsor

Phase 1
Phase

NCT04580121 2020-000216-30 WP42004
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- With confirmed diagnosis of primary or secondary AML according to WHO classification 2016, with measurable disease. Eligible participants need to have received standard-of-care (SOC) and have no

other SOC options available Participants who are not willing to receive SOC will be not eligible. Two groups of participants (Group I - hematologic relapsed/refractory and Group II - molecular relapsed/ refractory) will be included
- Participants who have received hematopoietic stem cell transplant (HSCT) must have the HSCT performed # 90 days prior to the first dose of RO7283420 on Cycle 1 Day 1, having demonstrated hematological engraftment and do not have an active Graft versus Host Disease, not requiring immunosuppressive treatment (including but not limited to cyclosporine, tacrolimus, sirolimus, and mycophenolate), which must be stopped at least 28 days prior to the first dose of RO7283420 on Cycle 1 Day 1
- Eastern Cooperative Oncology Group (ECOG) performance status 0-2
- Peripheral blast counts =< 20,000/mm3 on Cycle 1 Day 1 prior to the first dosing
- Confirmed genotype of HLA-A*02
- Adequate renal (a creatinine clearance of >=50 mL/min as calculated according to the Cockroft-Gault formula) and adequate liver test results
- Male or female participants agree to use contraception and the abstinence requirements to prevent exposure of an embryo to the study treatment

Exclusion Criteria:

- Acute promyelocytic leukemia (APL)
- Core Binding Factor (CBF)-AML Note: participants with r/r CBF-AML after at least 2 salvage attempts can be enrolled into the study
- Group II only: participants with normal karyotype and a favorable molecular profile according to ELN guideline 2017
- Participants with active bacterial, fungal or viral infection considered by the Investigator to be clinically uncontrolled or of unacceptable risk upon the induction of neutropenia (i.e. participants who are or should be on antimicrobial agents for the treatment of active infection)
- Grade >= 2 glomerular proteinuria at screening or on Cycle 1 Day 1 prior to the first dosing.
- Another primary malignancy (other than AML) that requires active therapy. Adjuvant hormonal therapy is allowed
- Clinical evidence or history of central nervous system (CNS) leukemia
- Presence of extramedullary disease at screening
- Current or past history of CNS disease, such as stroke, CNS inflammation, epilepsy, CNS vasculitis, or neurodegenerative disease
- Participants who have a history of clinically significant liver disease, including liver cirrhosis (e.g. Child-Pugh class B and C) or participants who have a history of active or chronic infectious hepatitis unless serology demonstrates clearance of infection
- Participants who might refuse to receive blood products and/or have known hypersensitivity to any of the components of RO7283420, tocilizumab, or dasatinib